K063166

Section XII: 510(k) Summary of Safety and Effectiveness

SAFE MEDICAL DEVICES ACT OF 1990

510(k) Summary

DEC 2 2 2006

NAME OF FIRM: I.T.S. Implantat-Technologie-Systeme GmbH.
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Lassnitzhoehe A – 8301
AUSTRIA

510(k) FIRM CONTACT: Al Lippincott
Engineering Consulting Services, Inc.
3150 E. 200th St.
Prior Lake, MN 55372

TRADE NAME: Pelvic Reconstruction System (PRS)

COMMON NAME: Pelvic Bone Fixation Set

CLASSIFICATION: Plate, Fixation, Bone (see 21 CRF, Sec. 888.3030),
Pin, Fixation, Threaded (see 21 CRF, Sec. 888.3040)
Screw, Fixation, Bone (see 21 CFR, Sec. 888.3040),
Washer, Bolt, Nut (see 21 CFR, Sec. 888.3030)

DEVICE PRODUCT CODE: HRS

SUBSEQUENT PRODUCT CODE: JDW, HWC, HTN

SUBSTANTIALLY EQUIVALENT DEVICES
Synthes 3.5mm Low Profile Pelvic Reconstruction **(K031573)**
Stryker Trauma Pelvic Set **(K001614)**
Zimmer Pelvic Reconstruction Set
Synthes Sacral Bar System **(K001720)**
I.T.S. GmbH FR.O.H. Calcaneus Repair System **(K051642)**
Synthes 3.9mm Pelvic Screw **(K013044)**
I.T.S. Straight Plate with Angular Stability & Screw System **(K060156)**

DEVICE DESCRIPTION: The I.T.S. Pelvic Reconstruction System (PRS) encompasses a number of fracture fixation subsystems (multiple pelvic plate designs, sacral threaded rod, and cannulated screw & washer) for facture fixation and reconstruction of pelvic ring fractures in the pelvis.

The I.T.S. PRS Low Profile – Multiple Type – Pelvic Plating System consists of the following plate types: 1) A Straight Plate at a 2.5mm thickness with 10 to 14 hole length sizes, 2) A Curved Plate with a 108mm radius at a 2.5mm thickness with 4 to 16 hole length sizes, 3) A Curved Plate with a 88mm radius at a 2.5mm thickness also with 4 to 16 hole length sizes, 4) A Symphysis Plate at a 4.0mm thickness in both a 4 & 6 hole size, 5) A SacroIlliac-Joint (SIJ) L-Shaped Plate at a 2.5mm thickness in a left and right 5 hole size, and 6) A SIJ Closed Plate at a 2.5mm thickness in a 4 hole size.

All plate designs are low profile in thickness and made from CP Titanium. The PRS Pelvic Plating System also encompasses a number

of Cancellous (5.9mm std.compression & 5.9mm Locking screws) and Cortical (4.5mm std.compression screw) screw types and length sizes. All bone screws are pre-drilling and self-tapping in design and manufactured from high strength 6-4 Alloyed Titanium. All components (plates & screws) have a TIODIZE II surface treatment preparation.

The I.T.S. PRS *Sacral Rod System* consists of a threaded pin, wedge-shaped washers, and nut/locknut design with one end of the threaded pin having a trocar point. The assembled unit is used to stabilize ilio-iliac posterior pelvic ring disruption injuries. All components are manufactured from high strength 6-4 Alloyed Titanium material and have the TIODIZE II surface preparation.

The I.T.S. PRS *7.3mm Cannulated SIJ Traction Screw & Washer* is a pre-drilling, self-tapping, and back-tapping screw design for guided reduction of pelvic bone fractures. Washers (flat & curved) are available for use with the screw. All 7.3mm Cannulated Screws & washers are manufactured from high strength 6-4 Alloyed Titanium and have the TIODIZE II surface preparation.

INTENDED USE:

The ***intended use*** of the I.T.S. Pelvic Reconstruction System (PRS) is to stabilize one or more pelvic bone fractures in the pelvic ring area of the pelvis of an adult or pediatric patient which include the use of the following pelvic fracture fixation systems.

Indications for use of the I.T.S. PRS Low Profile - Multiple Type – Pelvic Plating System include:
1) Fracture reconstruction of the acetabulum, sacrum, illium, and entire pelvic ring,
2) Revision surgery of pseoduarthroses, non-unions and mal-unions,
3) Ilio-Iliac distance osteosynthesis,
4) Osteotomies,
5) Arthrodesis,
6) Sacroiliac joint dislocations, and
7) Symphysis pubis disruptures

Indications for use of the I.T.S. PRS Sacral Rod System include:
1) Fixation of fractures of the posterior pelvis,
2) Fixation of fractures of the posterior iliac spine,
3) Fixation of fractures of the posterior inferior iliac spine,
4) Dorsal stabilization of the posterior pelvic ring for unstable pelvic ring injuries,
5) Fixation of sacral fractures, and
6) Fracture dislocations of the sacro-iliac joint

Indications for use of the I.T.S. PRS 7.3mm Cannulated SIJ Traction Screw & Washer include fracture fixation of pelvic bone fractures where indicated and for periacetabular osteotomies.

The system(s) has not been studied in spinal use, and is not intended for use in vertebral column fracture or fusion procedures.

BASIS OF SUBSTANTIAL EQIVLAENCE:

The I.T.S. Pelvic Reconstruction System (PRS) is substantially equivalent to the Synthes, Zimmer, and Stryker pelvic reconstruction systems and the I.T.S. GmbH stabilizing bone plating systems.

SUMMARY OF SAFETY AND EFFECTIVENESS:

The I.T.S. Pelvic Reconstruction System (PRS) is shown to be safe and effective for use in 'pelvic ring' bone fracture fixation of the pelvis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

I.T.S Implantat-Technologie-Systeme GmbH
% Mr. Al Lippincott
Engineering Consulting Services, Inc.
3150 E. 200th Street
Prior Lake, Minnesota 55372

DEC 2 2 2006

Re: K063166
Trade/Device Name: Pelvic Reconstruction System (PRS)
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, JDW, HWC
Dated: October 13, 2006
Received: October 18, 2006

Dear Mr. Lippincott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0210 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Bruch MD

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) NUMBER: K063166

DEVICE NAME: **PELVIC RECONSTRUCTION SYSTEM (PRS)**

The ***intended use*** of the I.T.S. Pelvic Reconstruction System (PRS) is to stabilize one or more pelvic bone fractures in the 'pelvic ring' area of the pelvis of an adult or pediatric patient which include the use of the following pelvic fracture fixation systems.

Indications for use of the I.T.S. PRS Low Profile - Multiple Type – Pelvic Plating System include:
1) Fracture reconstruction of the acetabulum, sacrum, illium, and entire pelvic ring,
2) Revision surgery of pseoduarthroses, non-unions and mal-unions,
3) Ilio-Iliac distance osteosynthesis,
4) Osteotomies,
5) Arthrodesis,
6) Sacroiliac joint dislocations, and
7) Symphysis pubis disruptures

Indications for use of the I.T.S. PRS Sacral Rod System include:
1) Fixation of fractures of the posterior pelvis,
2) Fixation of fractures of the posterior iliac spine,
3) Fixation of fractures of the posterior inferior iliac spine,
4) Dorsal stabilization of the posterior pelvic ring for unstable pelvic ring injuries,
5) Fixation of sacral fractures, and
6) Fracture dislocations of the sacro-iliac joint

Indications for use of the I.T.S. PRS 7.3mm Cannulated SIJ Traction Screw & Washer include fracture fixation of pelvic bone fractures where indicated and for periacetabular osteotomies.

The system(s) has not been studied in spinal use, and is not intended for use in vertebral column fracture or fusion procedures.

Prescription Use X AND/OR Over-The-Counter-Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Barbara Buchinski

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063166